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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,935	12/20/1999	VITALIY ARKADYEVICH LIVSHITS	0010-1070-0	1750

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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1656

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/466,935

Applicant(s)

LIVSHITS ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005 and 29 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,40,43,46,49-52,55,58,61 and 64-80 is/are pending in the application.
- 4a) Of the above claim(s) 49-52,55,58,61 and 64-72 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73-80 is/are allowed.
- 6) ☒ Claim(s) 37,40,43 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/16/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/2005 has been entered.

[2] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[3] Claims 37, 40, 43, 46, 49-52, 55, 58, 61, and 64-80 are pending in the application.

[4] Applicants' amendment to the claims, filed 3/14/2005, and supplemental amendments, filed 4/28/2005, and 4/29/2005, are acknowledged. The supplemental amendments filed 4/28/2005 and 4/29/2005 appear to be exact duplicates and have been treated as such. The listing of the claims filed 4/29/2005 replaces all prior versions and listings of the claims.

[5] A Notice of Non-Compliant Amendment was mailed on 7/19/2005 in response to the claim amendment filed 4/29/2005. The examiner's reasoning for holding the amendment non-compliant was that certain claims, e.g., claim 64, depend from withdrawn claims and therefore should be identified as "withdrawn" rather than as

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"previously presented." Ms. Cermak contacted the examiner by telephone and indicated that the Notice should be withdrawn as only the examiner can withdraw claims. In order to clarify the matter, the examiner contacted a representative of the Office of Patent Legal Affairs (OPLA). It is noted that the OPLA representative supported the examiner's position and indicated that the holding of non-compliance is proper. However, as the Office has provided no guidance regarding the proper claim status identifier in this situation, it was agreed to in a telephone conversation with Ms. Cermak that the Notice would be withdrawn and an Office action on the merits would be forthcoming.

[6] Receipt of an information disclosure statement (IDS), filed 6/16/2005, is acknowledged.

[7] Applicant's arguments filed 3/14/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[8] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Election/Restriction

[9] Claims 73-76 appear to be in a condition for allowance. In accordance with rejoinder practice according to MPEP 821.04, claims 77-80, which are drawn to methods of using the products of claims 73-76, have been rejoined with the claims of the elected invention and are being examined on the merits.

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[10] Claims 49-52, 55, 58, 61, and 64-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/30/2001.

[11] Claims 37, 40, 43, 46, and 73-80 are being examined on the merits.

Information Disclosure Statement

[12] All references cited in the IDS filed 6/16/2005 have been considered by the examiner. A copy of Form PTO-1449 is attached to the instant Office action.

[13] If the examiner has inadvertently overlooked an IDS that has previously been filed in the instant application, applicants' cooperation is requested in alerting the examiner to this IDS in the response to this Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

[14] Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is unclear in the recitation of "a DNA coding for the protein" in line 2. Claim 46 depends from claim 43 and based upon antecedent basis, it would appear that "the protein" refers to SEQ ID NO:4. However, it appears that "the protein" is meant to refer to SEQ ID NO:2 instead. It is suggested that applicants clarify the meaning of the claim.

Claim Rejections - 35 USC § 112, First Paragraph

[15] The written description rejection of claims 37, 40, 43, and 46 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the rejection is overcome by amendment.

Applicants' argument is not found persuasive. The claims are drawn to a genus of *Escherichia* bacteria that are modified to increase a copy number of a DNA encoding SEQ ID NO:4 and optionally wherein the genus of *Escherichia* bacteria is further modified to increase a copy number of a DNA encoding SEQ ID NO:2. The claims do not specify how the genus of *Escherichia* bacteria is modified to increase copy number. In this case, the genus encompasses widely variant species of modified *Escherichia* bacteria, including bacteria having a modification of the endogenous promoter that controls expression of SEQ ID NO:2 and 4, modification of an endogenous transcription factor that controls expression of SEQ ID NO:2 and 4, and any other modifications that result in an increased copy number of the encoding nucleic acids. The specification discloses only two representative species of the claimed *Escherichia* bacterium, *i.e.*, an *Escherichia* bacterium transformed with an expression vector, wherein the expression vector encodes the polypeptide of SEQ ID NO:2 and optionally wherein the bacterium is further transformed with an expression vector encoding the polypeptide of SEQ ID NO:4. These representative species fail to be representative of the widely variant

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species as encompassed by the genus of modified *Escherichia* bacteria. Given the lack of description of a representative number of polynucleotides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[16] The scope of enablement rejection of claims 37, 40, 43, and 46 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the rejection is overcome by amendment.

Applicants' argument is not found persuasive. As maintained in previous Office actions, the specification, while being enabling for an *Escherichia* bacterium transformed with an expression vector, wherein the expression vector encodes the polypeptide of SEQ ID NO:2 and optionally wherein the bacterium is further transformed with an expression vector encoding the polypeptide of SEQ ID NO:4, does not reasonably provide enablement for an *Escherichia* bacterium modified to increase a copy number of a DNA encoding the polypeptide of SEQ ID NO:2 and optionally encoding the polypeptide of SEQ ID NO:4. Claims 37, 40, 43, and 46 are so broad as to encompass an *Escherichia* bacterium modified to increase a copy number of a DNA encoding the polypeptide of SEQ ID NO:2 and optionally encoding the polypeptide of SEQ ID NO:4, wherein the bacterium is modified by any method, e.g., a modification of the endogenous promoter that controls expression of SEQ ID NO:2 and 4 and/or

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modification of an endogenous transcription factor that controls expression of SEQ ID NO:2 and 4. However, the specification's teachings and disclosed working examples, *i.e.*, an *Escherichia* bacterium transformed with an expression vector, wherein the expression vector encodes the polypeptide of SEQ ID NO:2 and optionally wherein the bacterium is further transformed with an expression vector encoding the polypeptide of SEQ ID NO:4, fail to provide the necessary guidance to enable a skilled artisan to make the full scope of claimed bacteria. In view of the lack of guidance and working examples, it is highly unpredictable as to which modifications to a bacteria will successfully result in an increased copy number of an encoding DNA. Further, it is noted that the art typically does not engage in making all modifications to a bacteria in order to increase a copy number of an encoding DNA. As such, the examiner maintains the position that undue experimentation is required to make all bacteria as encompassed by the scope of the claims.

Conclusion

[17] Status of the claims:

Claims 37, 40, 43, 46, 49-52, 55, 58, 61, and 64-80 are pending.

Claims 49-52, 55, 58, 61, and 64-72 are withdrawn from consideration.

Claims 73-80 appear to be in a condition for allowance.

Claims 37, 40, 43, and 46 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-

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272-0942. The examiner can normally be reached on Monday to Thursday and on alternate Fridays, 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
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